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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,379	08/15/2001	Christian Kropf	2006-219/H03763	8884
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PAUL & PAUL 2000 MARKET STREET Suite 2900 PHILADELPHIA, PA 19103-3229			EXAMINER ROBERTS, LEZAH	
			ART UNIT 1612	PAPER NUMBER
			MAIL DATE 01/07/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

09/868,379

**Applicant(s)**

KROPF ET AL.

**Examiner**

LEZAH W. ROBERTS

**Art Unit**

1612

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8,9,13-16 and 20-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8,9,13-16 and 20-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

## DETAILED ACTION

This Office Action is in response to the Amendment filed September 30, 2008. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Claims*

#### **Claim Rejections - 35 USC § 112 – New Matter (New Rejection)**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8, 9, 13-16 and 20-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite the limitation "acidic aqueous solution of water soluble calcium salts and aqueous solutions of water-soluble phosphate or fluoride salts at increased pH using an aqueous alkali ammonia and in the presence of". The specification does not appear to support solutions of fluoride salts being utilized in this method.

**Claim Rejections - 35 USC § 103 - Obviousness (Previous Rejection)**

Claims 8, 9, 13-16 and 20-25 were rejected under 35 U.S.C. 103(a) as being unpatentable over Rudin et al. (US 6,919,070) in view of Bagchi et al. (US 5,560,932). The rejection is maintained.

**Applicant's Arguments**

Applicant argues the hydroxyapatite disclosed by Rudin et al. is pure hydroxyapatite crystals whereas the components of the instant invention have a water-soluble protective coating. In regards to Bagchi et al., the particles of the reference are made from a different process than the hydroxyapatite of the instant claims. Bagchi et al. dissolves the components in an aqueous base followed by the addition of an aqueous surfactant solution followed by the addition of an acid solution to form a nanoparticulate dispersion. Applicants' precipitation reactions start with acidic solutions of calcium salts and are carried out at an increased pH using an aqueous alkali or ammonia. Applicant further asserts, in the claimed particles, the colloid forms intermolecular cross-linkages, whereas the compositions of Bagchi et al. do not.

**Examiner's Response**

Although the hydroxyapatite of Rudin are pure hydroxyapatite, the teachings of Bagchi et al. would motivate one of ordinary skill in the art to coat the hydroxyapatite to inhibit aggregation due to inter-particle attractive forces. In regards to the method of

making the colloidal system, the instant disclosure teaches several ways to make the colloidal systems of the instant claims (see page 7 of the instant specification). It appears not all of the methods of making the product of the instant claims required an initial acidic solution in order to make the compositions of the instant claims. Further, the product of the instant claims and the product of the combined reference have the same function as being used in an oral composition and restoring dental enamel. The prior art product appears to differ from the claim product only in the method of obtaining the product. The burden of persuasion is on Applicant to show that the claimed product exhibits unexpected properties compared with that of the prior art. See MPEP 2144.04. Although Applicant asserts a material with different properties is yielded from the procedures of the instant claims than what is taught in the combination of references, there appears to be no evidence to support that the compositions have different properties provided in the instant disclosure or the filed Declarations. Note that the burden is higher for applicant due to the "peculiar nature" of product by process claims, as discussed therein.

*Declarations by Christian Kropf*

The Declarations by Christian Kropf discuss the references. The Declaration asserts that Rudin et al. disclose pure hydroxyapatite crystals which are different from those of the instant claims. In regards to Bagchi et al., the Declaration discloses the dispersions of the reference are made by different processes and therefore lead to compositions with different properties. Bagchi et al. disclose the compositions are made

by dissolving the pharmaceutical agent in an alkaline solution, followed by the addition of a surfactant. The particles are then precipitated out of solution by the addition acid. In the instant case the hydroxyapatite particles are formed by initially combining an acidic calcium solution with aqueous solutions of phosphate salts. The pH of the mixture is raised with an aqueous alkali or ammonia to form the calcium salts of the instant claims. The Declaration further asserts Bagchi et al. teach the surface modifier physically adheres to the surface of the particles but is free of intermolecular linkages between the molecules of the modifier and between the modifier and the particles due to the lack of chemical bonds between the surface modifier and drug particle. The particles of the instant claims have a more intense structure in which, the colloid forms intermolecular cross-linkages, whereas the particles of Bagchi et al. do not. The Declarations are not persuasive.

Examiner's Response to the Declaration

As mentioned above, although the hydroxyapatite of Rudin et al. is pure, the combined teachings of Rudin et al. and Bagchi et al. suggest the compositions of the instant claims. Although the methods of making the compositions vary and Applicant asserts the instant compositions have different properties than the properties disclosed by Bagchi et al., Applicant has provided no objective evidence to support this assertion. It cannot be determined, without a evidence if the products from the different methods yield products with different properties such as the intermolecular cross-linkages between the hydroxyapatite and the coating.

Claims 8, 9, 13-16 and 20-25 are rejected.

No claims allowed.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/  
Examiner, Art Unit 1612

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612